

REMARKS

Claims 1-16 and 18-26 are pending in this application. By this Amendment, claims 1, 2, 16 and 18 are amended, and claims 19-26 are added. No new matter is added. Support for the amendments to the claims and for the new claims can be found in the specification, for example, at pages 7, 8 and 42-44.

The courtesies extended to Applicants' representative by Examiner Saucier at the interview held December 24, 2008, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below, which constitute Applicants' record of the interview.

I. Information Disclosure Statement

The Office Action does not consider some of the references of the PTO Form 1449 filed May 9, 2008 because either the references allegedly do not have a statement of relevance of the citation is incomplete. Without conceding the propriety of these assertions, Applicants address these assertions in a Supplemental Information Disclosure Statement concurrently filed herewith. Additionally, Applicants respectfully traverse some of the Office Action's assertions.

With respect to a statement of relevance for the French references, reference numbers 11 and 15 of the May 9, 2008 Information Disclosure Statement, these references were cited in International Search Reports that were previously disclosed and cited in the parent application, U.S. Patent Application No. 09/162,128. The Supplemental Information Disclosure Statement includes these International Search Reports for the Examiner's convenience.

With respect to the other references, Applicants respectfully traverse the Office Action's assertions that citations for the non-patent publications that are books must comply

with MPEP §707.05(e) III. This MPEP section relates to the citation requirements for the Examiner and not for Applicants.

Applicants respectfully assert that all references previously and currently submitted satisfy the requirements of 37 C.F.R. §1.98(b), because they include author (if any), title, relevant pages of the publication, date and place of publication (which refers to the name of the journal, magazine, or other publication in which the information being submitted was published). Additionally, some references do not include all of the above information, because it does not pertain to the publication; for example, references 12 and 18 do not have any page numbers, and thus these citations should be considered to be complete.

Consideration of the references is thus respectfully requested.

II. The Claims Satisfy the Requirements of 35 U.S.C. §112, Second Paragraph

Claims 1-16 and 18 are rejected under 35 U.S.C. §112, second paragraph. The rejection is respectfully traversed.

The Office Action asserts that the term "exposing," recited in claim 1 is unclear. Without conceding the propriety of the rejection of claim 1, as agreed during the personal interview, claims 1 and 16, as amended, recite "contacting," which obviates the rejection.

The Office Action also asserts that the term "the sensed characteristics relate to," in claims 13-15, is unclear because the "degree of relationship" required cannot be determined. These assertions are respectfully traversed.

The term "sensed characteristics relate to," in claims 13-15, is clear to a person possessing the ordinary level of skill in the pertinent art. It is clear from these claims that the sensed characteristics relate to, i.e., have a relationship to, at least one of absorption, distribution, metabolism and excretion, as recited in claim 13; at least one of pharmacokinetics, pharmacodynamics and toxicity, as recited in independent claim 14; and/or at least one of determining what the substance is doing to the at least one organ and what the

at least one organ is doing to the substance, as recited in independent claim 15. The degree of relationship between the sensed characteristics and the above-described items is not necessary to understand the metes and bounds of the claimed subject matter. Thus, as tentatively agreed during the personal interview, the relationship between the sensed characteristics and above-described items associated with the substance and/or organ is clear.

The Office Action also asserts that the term "sensing" as recited in claim 16 is unclear. This assertion is respectfully traversed.

With respect to claim 16, Applicants respectfully assert that this claim does not recite a step of "sensing," and thus contrary to the Office Action's assertion, this claim does not require that "sensing" takes place.

For at least these reasons, claims 1 and 13-16, and claims 2-12 and 18 depending therefrom, satisfy the requirements of 35 U.S.C. §112, second paragraph. Withdrawal of the rejection is thus respectfully requested.

III. The Claims Define Patentable Subject Matter

Claims 1-16 and 18 are rejected under 35 U.S.C. §103(a) over International Patent Publication No. WO 94/06292 to Sadri in combination with International Patent Publication No. WO 96/29865 to Fahy et al. (hereinafter "Fahy") and Journal Publication "The In-Vitro Inhibition of Rat Alloantigen Presentation by Immunotoxins-Implications for Allografting," Clin. Exp. Immunol. (1989) 76, 132-137 by Wiley et al. (hereinafter "Wiley"), or Journal Publication "The Effectiveness of Anti-IA-Immunotoxins in the Suppression of MLR^{1, 2}," Transplantation Vol. 42, No. 2 by Nakahara et al. (hereinafter "Nakahara") and "Handbook of Human Tissue Sources", Chapter 3, page 72, by Eiseman et al. (hereinafter "Eiseman") in light of the statement from "Human Tissue and Organ Resource for Research", from National Institutes of Health (hereinafter "NIH statement"). The rejection is respectfully traversed.

As an initial matter, the NIH statement cannot be relied upon in the rejection as it does not qualify as prior art to this application. The NIH statement is dated July 15, 2008, the only date provided. The instant application was filed on February 2, 2004. Thus, the NIH statement does not qualify as prior art. For at least this reason, withdrawal of the rejection is thus respectfully requested.

However, in order to expedite allowance, Applicants address the rejection below, without the reliance upon the NIH statement.

None of the applied references teaches or renders obvious the steps of "analyzing the at least one organ to determine whether the organ is suitable to be transplanted; and based on a determination that the organ is not suitable to be transplanted," performing the additional steps of perfusing the organ, contacting the organ with at least one test substance and gathering data, as recited in independent claim 1, and as similarly recited in independent claim 16.

The Office Action acknowledges that Sadri is silent with respect to "suitability or unsuitability for transplantation of the organ." The Office Action further asserts that "[t]he use of an organ which is not suitable for transplantation in a method of research such as the testing compounds in physiological or pharmaceutical research as taught by [Sadri] is well within the purview of one of skill in the art and it is known that banks have been available to researchers for the express purpose of donating organs unsuitable for transplantation for in research. One of skill in the art may use an organ which has been determined to be unsuitable for transplantation in the absence of evidence to the contrary especially because such banks and exchange resources have been instituted for research on unsuitable organs." These assertions are respectfully traversed.

As acknowledged by the Office Action, Eiseman states that the Human Tissues and Organs for Research (HTOR) unit focuses on retrieval and distribution of tissue and organs.

Eiseman states that the HTOR unit focuses on the retrieval and distribution of tissues and organs from autopsy and surgical procedures, and specimens obtained from eye and tissue banks. The fact that discarded organs and tissues are available does not necessarily mean that these organs and tissues were discarded because they were analyzed and determined to be unsuitable for transplantation. Eiseman does not disclose this step. In fact, these organs may be retrieved from autopsies, as noted above, and thus, these organs would never have been analyzed to determine whether they were suitable for transplantation.

Additionally, the organs distributed through the HTOR are typically frozen. Accordingly, they are never considered to be suitable for transplantation. Thus, Eiseman does not teach or render obvious the steps of analyzing and determining, as recited in independent claims 1 and 16.

Further, even if the teachings of Eiseman, i.e., discarded organs and tissues may be available, were combined with Sadri, it would not result in the claimed invention. One of ordinary in the skill in the art would not analyze an organ distributed by the HTOR to determine its suitability for transplantation because they are discarded and typically frozen. Thus, one of ordinary in skill in the art would not have been motivated to modify the method of Sadri to include the step of analyzing based on the teachings of Eiseman.

Further, the other applied references do not remedy the above-described deficiencies of Sadri and Eiseman.

Thus, for at least these reasons, independent claims 1 and 16 are patentable over the applied references. Further, claims 2-15 and 18, which depend from claims 1 and 16, respectively, are also patentable over the applied references for at least the reasons discussed above, as well as for the additional features they recite. Withdrawal of the rejection is thus respectfully requested.

Further, new claims 19-26 are patentable over the applied references for at least the reasons discussed above with respect to claims 1 and 16 from which they depend, as well as for the additional features they recite. For example, none of the applied references teaches or renders obvious that the at least one organ that is analyzed and perfused was preserved in condition for transplantation, as recited in claims 19 and 20. As discussed above, Eiseman merely discloses the distribution of (frozen) organs and tissues discarded after autopsies or surgeries.

Further, none of the applied references teaches or renders obvious generating measurement data based on the sensed characteristics and comparing the measurement data to characteristics of the at least one test substance, as recited in claims 23 and 24.

IV. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachments:

Amendment Transmittal
Petition For Extension of Time
Request For Continued Examination

Date: January 16, 2009

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